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Resonance Innovations, LLC
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FEB 2 6 2014

Section 8. 510(k) Summary	K140282
Submitter's Name:	Resonance Innovations LLC
Submitter's Address:	9840 South 140th St., Suite 8 Omaha, NE 68138
Submitter's Telephone:	402-934-2650
Submitter's Contact:	Randall Jones, President
Date 510(k) Summary prepared:	February 14th, 2014
Proprietary Name:	ST SENSE NV 8 Array Coil
Common or Usual Name:	MRI coil(s)
Classification Name:	Coil, Magnetic Resonance, Specialty
Classification Code:	MOS
Predicate Device:	1.5T Pediatric Head/Spine Array Coil

Description of the Device

The 8 individual coils that comprise the ST SENSE NV 8 Array Coil (Neurovascular Array) interface with a 1.0 Tesla, 8-channel Panorama MRI scanner. Between the device and its predicate, there are slight variations in physical size of electrical and physical aspects (to accommodate focus of anatomies) The designs and materials used to manufacture the individual coils are nearly identical and are no different from standard MRI coil technology that has existed for years. The geometry of each coil housing has been formed by utilizing a rigid housing that disconnects to facilitate both close coupling of the imaging coil's region-of-sensitivity to the anatomy of interest on a patient anatomy, and ease of entry to each patient. All employ similar blocking, impedance matching and integrated pre-amplifier circuitry.

Device Model Number	Device Description
908GE1001	ST SENSE NV 8 Array Coil

Table 1 Device Description

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Indications for Use

The intended use for this 1.0T 8-channel Neurovascular Coil is to facilitate diagnostic targeting imaging of brain, neck and upper chest that may be interpreted by a trained physician.

- To collect image data throughout the region of the head, neck and chest region of the patient using a Philips vertical-field 1.0T MR scanner.
    - Various regions of the Brain, including brainstem, pituitary, IAC, and orbits, intra cerebral vascular structure, soft tissue of the facial area, arteries between the aortic arch and the Circle of Willis, soft tissue in the anterior neck, pediatric head/neck, cervical spine, long top and brachial plexus, and with the ability to scan feet and ankles.

Technological Characteristics

The comparison between the predicate and the current submission is described, below.

1. Design. This submission is for a Receive-Only Coil for an MRI System. It is a dedicated coil that may give diagnostic quality images of the tops of the lungs all the way to the brain, with angiography of the entire anatomy within this range. It is an 8-channel receive coil with all channels designed to work at once, in conjunction with the system Body Coil. The predicate covers very similar anatomy, yet for a different system and field strength.
2. Material. It is largely polycarbonate, painted, and with Ultem latching pieces. The distinction between the predicate and current submission is non-substantive in that they both have insulating qualities proven by dielectric withstand testing, and have passed liquid ingress testing.
3. Chemical Composition. Both products, the predicate and current submission, have biocompatible construction, using polycarbonate with enamel paint, as demonstrated by cytotoxicity testing and by their history of use in previously cleared devices.
4. Energy Source. Both of these products are receive-only coils not generating their own power, but rather stimulated by the MRI system as the energy source.

Non-Clinical Tests

The coils have similar dimension in the head area and have induced similar fields by the transmit coil (Body Coil) that stimulates them. The predicate and current submission were compared by similar risk management efforts, as listed below, and determined to be substantially equivalent.

- Sensitivity profile
- SNR Analysis

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- Hazard Analysis
- FMEA
- Blocking Analysis
- Heat Tests

Clinical Tests

Analyses in all 3 planes (sagittal, coronal and transverse) were run to show that the anatomies of the submitted and predicate coils have substantial equivalence; the predicate device images the complete brain and neck regions, and the current Neurovascular submission images anatomies between brain and lung tops.

Final Discussion

As described in the Design section, above, the submission is also for eight loops dedicated over a similar region of interest as its predicate, with the coils offering no energy source, and exhibiting strong decoupling; thus, the study determines that the submitted device is as safe, as effective, and performs as well or better than the legally-marketed device on the target anatomies, in its respective field strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Resonance Innovations, LLC
% Mr. Randall Jones
President
9840 S. 140th Street, Suite 8
OMAHA NE 68138

February 26, 2014

Re: K140282
Trade/Device Name: ST SENSE NV 8 Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: January 31, 2014
Received: February 4, 2014

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k140282

Device Name
ST SENSE NV 8 Array Coil

Indications for Use *(Describe)*

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-To collect image data throughout the region of the head, neck and chest region of the patient using a Philips vertical-field 1.0T MR scanner.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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